

REMARKS

A final Office Action in this matter was issued on January 3, 2005. The applicants have filed a Request for Continued Examination and request entry of the present amendment. Claims 1-10, 14-26, 28, 31-44, and 46-55 are now present in this case. Claims 1 and 20 are amended.

The Office Action raises an objection to claim 1 due to an informality. For purposes of clarity, the applicants agree that an individual cannot be classified into both an ARA sub-population and an ARU sub-population. However, the relevant portion of Claim 1 is defining the two sub-populations. That is, the sub-populations are defined as ARA and ARU. Accordingly, the applicants respectfully request that the Examiner withdraw the objection to claim 1.

Claims 1-10, 14-26, 28, 31-35 stand rejected under 35 U.S.C. § 102(a) as anticipated by “well-known breast cancer screening methods established by the National Institutes of Health (NIH).” The applicants respectfully traverse this rejection and request reconsideration.

In a prior Office Action, claims were rejected on the basis of U.S. Patent Number 6,059,724 to Campell, et al. In responding to that Office Action, the applicants pointed out that Campell describes a predictive system in which various factors are assessed to determine that the likelihood that an individual will be affected by a biological condition within some period of time in the future. The applicants have consistently indicated that the claimed invention is not a forward-looking predictive process. Rather, subjects in a population are categorized into sub-populations, two of which are defined as “at risk and affected (ARA)” and “at risk and unaffected (ARU).” As previously discussed with the Examiner, the subjects in the group defined as ARU are not intended to identify individuals who are at greater risk for being affected in the future. Rather, the term ARU, as used herein, is intended to define individuals that ought to be affected by the biological condition at the present time, but for some unidentified factor that prevents them from being presently affected by the biological condition. As noted in the specification of the pending application, a process is described “to determine the genetic influences that allow people to remain healthy,

even under conditions where they are expected to be sick." (Specification, page 5.) This is significantly different from a future predictive process, as taught by Campell. In a prior telephone conference with the Examiner, the Examiner suggested claim language that would differentiate the claimed invention over Campell.

Despite incorporating the suggested language, the Office Action dated January 3, 2005 is a final rejection based on NIH studies. However, it should be noted that the NIH studies, in effect, describe the same predictive analysis presented by Campell. That is, the NIH studies revolve around the discovery of a genetic mutation of genes identified as BRCA1 and BRCA2. Reference A indicates the purpose of the study is to "explore whether different forms, or variants, of genes are related to a person's risk of developing breast cancer." (*Emphasis added.*) In that sense, the new references only provide an example of the concepts described by Campell.

Reference B discusses the advantages and disadvantages of genetic testing to detect the BRCA1 and BRCA2 genetic mutations. A positive result (*i.e.*, detection of a mutation) indicates that the individual has an increased risk of cancer, but Reference B states that "a positive result only provides risk information and cannot tell a person whether or when cancer might develop." (see page 2). Thus, the genetic testing described in reference B clearly are directed at predictive risks for future contraction of cancer and does not suggest population classification.

Similarly, reference C describes patient counseling and indicates future risk for a number of different diseases. (see table 2). These risks are clearly predictive risks based on statistical population analysis, but does not suggest any population classification process.

Reference D is directed to the use of data "to develop a model for estimating the risk of breast cancer for women in a program of annual mammographic screening who have had no previous breast cancer and who have no evidence of breast cancer at the time of their initial screening mammogram." (see page two). These are models that predict future risk of contracting breast cancer. It is clear that the study is not directed to any individuals who have already contracted cancer and thus teaches directly away from a categorization defined as ARA.

Reference E describes a statistical analysis that allows a woman to estimate the risk for breast cancer over a five-year period and over her lifetime (to age 90). (See page 1.) This is a predictive risk assessment.

In contrast to the cited references, claim 1 is a method claim that recites *inter alia* “classifying the population into at least two phenotypic sub-populations defined as at risk and affected (ARA) whose members have ever been effected by the selected biological condition, and at risk and unaffected (ARU), whose members remain unaffected by the selected biological condition and whose unaffected status is inconsistent with their historical risk factors.” The NIH studies do not teach, or even suggest, such categorization.

The NIH studies do not teach or suggest an ARA group. Reference A is a proposal to assess future risk of a person’s developing breast cancer. In one sentence the study states that it will “try to determine if people with breast cancer have different gene variance from people without the disease.” It should be noted that this is a hypothesis rather than a teaching. It is insufficient to qualify as an enabling disclosure. Even if *arguendo*, one were to consider this as an adequate teaching, it does not teach or suggest the categorization of subjects into an ARA and an ARU group. People without the disease referred to in reference A are not necessarily those who would be classified in an ARU group. Indeed, those with the genetic mutation of the BRCA1 and BRCA2 genes, may still be “without the disease.” Thus, a mere statement that a study proposes to determine if people with breast cancer have different gene variance from people without the disease does not teach or suggest the invention recited in claim 1. As discussed above, references B-E are clearly predictive in nature and do not propose any categorization, such as recited in claim 1. Indeed, they teach directly away from the recitation of claim 1 by describing a predictive process in which future risk of contracting breast cancer is determined. Accordingly, claim 1 is clearly allowable over the cited references. Claims 2-10, 14-19, and 47-50 are also allowable in view of the fact that they depend from claim 1, and further in view of the recitation in each of those claims.

Claim 20 is a computer implemented method of data analysis in which disease characteristics of a selected biological condition and risk characteristics of the

selected biological condition are defined. Affected status and risk status for a plurality of subjects are determined and "based on the affected status and the risk status classifying each of the plurality of subjects into a predetermined category for the selected biological condition selected from a group comprising at risk affected (ARA), whose members have ever been affected by the selected biological condition, and at risk, unaffected (ARU), whose members remain unaffected by the selected biological condition and whose unaffected status is inconsistent with the risk status." As discussed above, the individual documents in the NIH studies are all predictive in nature and do not teach or suggest categorization into ARA and ARU categories wherein the ARA group has members that have ever been affected by the selected biological condition and an ARU group whose members remain unaffected by the selected biological condition and whose unaffected status is inconsistent with the risk status. Accordingly, claim 20 is clearly allowable over the cited references. Claims 21-26, 28, 31-40, and 51 are also allowable in view of the fact that they depend from claim 20, and further in view of the recitation in each of those claims.

The applicants have made a good faith effort to place all claims in condition for allowance. If questions remain regarding the present application, the Examiner is invited to contact the undersigned at (206) 628-7640.

Respectfully submitted,
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